(1) By certified mail to purchasers of the product and to subsequent transferees.

(2) By certified mail or other more expeditious means to dealers and distributors.

(d) Where products were sold under a name other than that of the manufacturer of the product, the name of the individual or company under whose name the product was sold may be used in the notification required by this section.

§ 1003.22 Copies of communications sent to purchasers, dealers or distributors.

(a) Every manufacturer of electronic products shall furnish to the Secretary a copy of all notices, bulletins, or other communications sent to the dealers or distributors of such manufacturers or to purchasers (or subsequent transferees) of electronic products of such manufacturer regarding any defect in such product or any failure of such product to comply with an applicable Federal standard.

(b) In the event the Secretary deems the content of such notices to be insufficient to protect the public health and safety, the Secretary may require additional notice to such recipients, or may elect to make or cause to be made such notification by whatever means he deems appropriate.

Subpart D—Exemptions From Notification Requirements

§ 1003.30 Application for exemption from notification requirements.

(a) A manufacturer may at the time of giving the written confirmation required by §1003.20 or within 15 days of the receipt of any notice from the Secretary pursuant to §1003.11(a), apply for an exemption from the requirement of notice to the persons specified in §1003.10(b).

(b) The application for exemption shall contain the information required by §1003.20 and in addition shall set forth in detail the grounds upon which the exemption is sought.

§ 1003.31 Granting the exemption.

(a) If, in the judgment of the Secretary, the application filed pursuant to §1003.30 states reasonable grounds for an exemption from the requirement of notice, the Secretary shall give the manufacturer written notice specifying a reasonable period of time during which he may present his views and evidence in support of the application.

(b) Such views and evidence shall be confined to matters relevant to whether the defect in the product or its failure to comply with an applicable Federal standard is such as to create a significant risk of injury, including genetic injury, to any person and shall be presented in writing unless the Secretary determines that an oral presentation is desirable. Where such evidence includes nonclinical laboratory studies, the data submitted shall include, with respect to each such study, either a statement that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance. When such evidence includes clinical investigations involving human subjects, the data submitted shall include, with respect to each clinical investigation either a statement that each investigation was conducted in compliance with the requirements set forth in part 56 of this chapter, or a statement that the investigation is not subject to such requirements in accordance with §56.104 or §56.105, and a statement that each investigation was conducted in compliance with the requirements set forth in part 50 of this chapter.

(c) If, during the period of time afforded the manufacturer to present his views and evidence, the manufacturer proves to the Secretary's satisfaction that the defect or failure to comply does not create a significant risk of injury, including genetic injury, to any person, the Secretary shall issue an exemption from the requirement of notification to the manufacturer and shall notify the manufacturer in writing specifying:

(1) The electronic product or products for which the exemption has been issued; and

(2) Such conditions as the Secretary deems necessary to protect the public health and safety.

(d) Any person who contests denial of an exemption shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

[38 FR 28628, Oct. 15, 1973, as amended at 41 FR 48269, Nov. 2, 1976; 42 FR 15676, Mar. 22, 1977; 50 FR 7518, Feb. 22, 1985]

PART 1004—REPURCHASE, REPAIRS, OR REPLACEMENT OF ELECTRONIC PRODUCTS

Sec.

AUTHORITY: 42 U.S.C. 263b–263n.

SOURCE: 38 FR 28629, Oct. 15, 1973, unless otherwise noted.

§ 1004.1 Manufacturer's obligation to repair, replace, or refund cost of electronic products.

(a) If any electronic product fails to comply with an applicable Federal standard or has a defect and the notification specified in §1003.10(b) of this chapter is required to be furnished, the manufacturer of such product shall;

(1) Without charge, bring such product into conformity with such standard or remedy such defect and provide reimbursement for any expenses for transportation of such product incurred in connection with having such product brought into conformity or having such defect remedied; or

(2) Replace such product with a like or equivalent product which complies with each applicable Federal standard and which has no defect relating to the safety of its use; or

(3) Make a refund of the cost of the product to the purchaser.

(b) The manufacturer shall take the action required by this section in accordance with a plan approved by the Secretary pursuant to §1004.6.

§ 1004.2 Plans for the repair of electronic products.

Every plan for bringing an electronic product into conformity with applicable Federal standards or for remedying any defect in such product shall be submitted to the Secretary in writing, and in addition to other relevant information which the Secretary may require, shall include:

(a) Identification of the product involved.

(b) The approximate number of defective product units which have left the place of manufacture.

(c) The specific modifications, alterations, changes, repairs, corrections, or adjustments to be made to bring the product into conformity or remedy any defect.

(d) The manner in which the operations described in paragraph (c) will be accomplished, including the procedure for obtaining access to, or possession of, the products and the location where such operations will be performed.

(e) The technical data, test results or studies demonstrating the effectiveness of the proposed remedial action.

(f) A time limit, reasonable in light of the circumstances, for completion of the operations.

(g) The system by which the manufacturer will provide reimbursement for any transportation expenses incurred in connection with having such product brought into conformity or having any defect remedied.

(h) The text of the statement which the manufacturer will send to the persons specified in §1003.10(b) of this chapter informing such persons;

(1) That the manufacturer, at his expense, will repair the electronic product involved,

(2) Of the method by which the manufacturer will obtain access to or possession of the product to make such repairs,

(3) That the manufacturer will reimburse such persons for any transportation expenses incurred in connection with making such repairs, and

(4) Of the manner in which such reimbursement will be effected.

(i) An assurance that the manufacturer will provide the Secretary with progress reports on the effectiveness of